

16090045

510(k) Summary
as required by 807.92

1. Company Identification

EIZO NANAO CORPORATION

153 Shimokashiwano-cho, Hakusan-shi, Ishikawa-ken, 924-8566, Japan

Tel: +81-76-274-2468

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JAN 28 2009

2. Official Correspondent

Hiroaki Hashimoto (Mr.)

Manager of Product Safety

3. Date of Submission

January 6, 2009

4. Device Trade name

Color LCD Monitor, RadiForce RX320

5. Common/Usual Name

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer : EIZO NANAO CORPORATION

Device Name : Color LCD Monitor

Model Name : RadiForce R31 and R31-C

510(k) No. : K052344

8. Description of Device

RadiForce RX320 is a 54cm (21.2") Color LCD display for medical image viewing. RX320 displays high-definition medical imaging.

9. Intended Use

RadiForce RX320 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. RadiForce RX320 does not support the display of mammography images for diagnosis.

10. Technological Characteristics

RadiForce RX320 is substantially equivalent to R31 and R31-C (K052344). Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. RX320 improved the brightness and contrast of the LCD module, and modified the calibration software. The brightness improved in 900 cd/m² from 400 cd/m². The contrast improved by it.

Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1.

Appendix 1: Comparison Table with Predicate Device

Items	R31	R31-C	RX320
510(k) Number	K052344		Not Provided
Panel Protector	Not provided	Provided	Optional
Panel Size and Type	53 cm (20.8") TFT Color LCD panel		54cm (21.2") TFT Color LCD panel
Pixel Pitch	0.207 x 0.207mm		0.21075 x 0.21075 mm
Cabinet Color	Black		Same as R31 and R31-C
Display Colors	10-bit: 1.06 billion (maximum) 8-bit: 16.77 million from a palette of 1.06 billion		Same as R31 and R31-C
Viewing Angles	H: 170°, V: 170°		Same as R31 and R31-C
Scanning Frequency (H, V)	31-127kHz, 59-61Hz (VGA Text: 69-71Hz, QXGA: 36-61Hz) Frame synchronous mode: 59-61Hz		31-127kHz, 29-61Hz (VGA Text: 69-71Hz) Frame synchronous mode: 59-61Hz
Native Resolutions	2048 x 1536 (portrait) /1536 x 2048 (landscape)		Same as R31 and R31-C
Brightness	400 cd/m ²		900 cd/m ²
Contrast Ratio	400 : 1 (typical)		1000 : 1 (typical)
DOT Clock	215 MHz		Same as R31 and R31-C
Response Time	50 ms (typical)		20 ms (typical)
Active Display Size (H x V)	318 x 424 mm		323.7 x 431.6 mm
Viewable Image Size	Diagonal: 529 mm		Diagonal: 540 mm
Luminance Calibration	Software (Optional) Photo-sensor (Optional)		Software (Optional) Photo-sensor (Optional) Digital Uniformity Equalizer
Input Signals	DVI Standard 1.0		Same as R31 and R31-C
Input Terminals	DVI-D 24 pin		Same as R31 and R31-C
USB Ports / Standard	1 upstream, 2 downstream		Same as R31 and R31-C
Power	AC100-120V, 200-240V, 50/60Hz		Same as R31 and R31-C
Power Management	DVI-DMPM		Same as R31 and R31-C
Dimensions (W x H x D)	With Stand: 368 x 515.5 mm - 597.5 x 209 mm Without Stand: 368 x 486 x 88.5 mm		Same as R31 and R31-C
Certifications & Standards	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-A, CCC		CE (Medical Device Directive), TUV/GM (EN60601-1), cTUVus (UL 60601-1, CSA C22.2 No. 601-1), CB(IEC60601-1), VCCI-B, FCC-B, Canadian ICES-003-B, c-Tick, RoHS

*The software used in RX320 is modified, refer to the "12. Information of Software used in RX320".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hiroaki Hashimoto
Manager of Product Safety
EIZO NANAO CORPORATION
153 Shimokashiwano-cho
Hakusan, Ishikawa-ken 924-8566
JAPAN

JAN 28 2009

Re: K090045

Trade/Device Name: Color LCD Monitor, (RadiForce RX320)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 6, 2009
Received: January 7, 2009

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

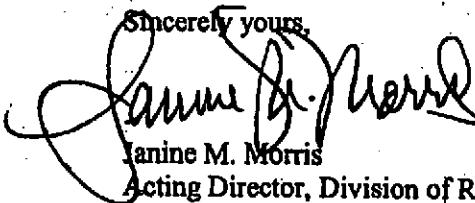
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.support/index.html>.

Sincerely yours,



Janine M. Morris

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number:

K090045

Device Name : Color LCD Monitor, RadiForce RX320

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John M. Whay
(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number *K090045*